Notice of Allowability	Application No.	Applicant(s)	
	10/006,740	MACGREGOR, ALEXANDER	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *applicant's request filed 1/24/08*.

2. ☒ The allowed claim(s) is/are *47, 48, 50-53 and 56-60 (claims are renumbered)*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *3/19/08* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dawn C. Russell on 3/11/08 and 3/19/08.

The application has been amended as follows:

In the claims,

Claims 49, 54 and 55: (Canceled)

Claims 61-74: (Canceled)

Amend claim 47 as follows:

47. (*currently amended*) 47. A dosage form for oral administration consisting of:

a compressed homogeneous mixture comprising:

a pharmacologically-active substance; and

a hydrostatic couple consisting of:

a) at least one crosslinked hydrodynamic fluid-imbibing polymer

selected from the group consisting of:

i) an acrylic-acid polymer cross-linked with allylsucrose or

allylpentaerythritol;

ii) one or more [starch derivatives] <u>high amylose starches</u> cross-linked by epichlorhydrin, phosphorous oxychloride ($POCl_3$), or sodium trimetaphosphate;

iii) a crosslinked polyglucan;

iv) a crosslinked polyethylenimine;

v) a crosslinked polyallylamine, and

vi) combinations thereof; and

b) at least one crosslinked hydrostatic pressure-modulating agent

selected from the group consisting of:

i) a homopolymer of cross-linked N-vinyl-2-pyrollidone;

ii) a rapidly expanding cross-linked cellulose derivative selected from the group consisting of cross-linked carboxymethyl cellulose, sodium starch glycolate, and combinations thereof ; and

iii) combinations thereof.

Amend claim 56 as follows:

56. (*currently amended*) A dosage form for oral administration consisting of:

a compressed homogeneous mixture comprising:

a pharmacologically-active substance; and

a hydrostatic couple consisting of:

a) at least one crosslinked hydrodynamic fluid-imbibing polymer

selected from the group consisting of:

i) an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol;

ii) one or more [starch derivatives] high amylose starches cross-linked by epichlorhydrin, phosphorous oxychloride ($POCl_3$), or sodium trimetaphosphate;

iii) a crosslinked polyglucan;

iv) a crosslinked polyethylenimine;

v) a crosslinked polyallylamine, and

vi) combinations thereof; and

b) at least one crosslinked hydrostatic pressure-modulating agent

selected from the group consisting of:

i) a homopolymer of cross-linked N-vinyl-2-pyrollidone;

ii) a rapidly expanding cross-linked cellulose derivative selected from the group consisting of cross-linked carboxymethyl cellulose, sodium starch glycolate, and combinations thereof; and

iii) combinations thereof; and

c) an expansion source.

The listing of claims below replaces all earlier versions:

The claims:

1-46. (Canceled)

47. (currently amended) A dosage form for oral administration consisting of:

a compressed homogeneous mixture comprising:

a pharmacologically-active substance; and

a hydrostatic couple consisting of:

a) at least one crosslinked hydrodynamic fluid-imbibing polymer

selected from the group consisting of:

i) an acrylic-acid polymer cross-linked with allylsucrose or

allylpentaerythritol;

ii) one or more [starch derivatives] high amylose starches cross-linked by epichlorhydrin,

phosphorous oxychloride ($POCl_3$), or sodium trimetaphosphate;

iii) a crosslinked polyglucan;

iv) a crosslinked polyethylenimine;

v) a crosslinked polyallylamine, and

vi) combinations thereof; and

b) at least one crosslinked hydrostatic pressure-modulating agent

selected from the group consisting of:

i) a homopolymer of cross-linked N-vinyl-2-pyrollidone;

ii) a rapidly expanding cross-linked cellulose derivative selected from the group consisting of cross-linked carboxymethyl cellulose, sodium starch glycolate, and combinations thereof ; and

iii) combinations thereof.

48. (NEW) The dosage form of claim 47, wherein said crosslinked polyglucan is selected from the group consisting of amylose containing diester or diether crosslinks, dextran containing diester or diether crosslinks, pullulan succinate containing diester or diether crosslinks, pullulan glutarates containing diester or diether crosslinks, and combinations thereof.

49. (Canceled)

50. (NEW) The dosage form of claim 47, wherein the pharmacologically-active substance is selected from the group consisting of analgesics, anti-inflammatories,

antimicrobials, amoebicidals, trichomonocidal agents, anti-Parkinson's, anti-malarials, anticonvulsants, anti-depressants, antiarthritics, anti-fungals, antihypertensives, antipyretics, anti-parasites, antihistamines, alpha-adrenergic agonists, alpha blockers, anesthetics, bronchial dilators, biocides, bactericides, bacteriostats, beta adrenergic blockers, calcium channel blockers, cardiovascular drugs, contraceptives, decongestants, diuretics, depressants, diagnostics, electrolytes, hypnotics, hormones, hyperglycemics, muscle relaxants, muscle contractants, ophthalmics, parasympathomimetics, psychic energizers, sedatives, sympathomimetics, tranquilizers, viricides, vitamins, non-steroidal anti-inflammatories, angiotensin converting enzyme inhibitors, polypeptides, proteins, and sleep inducers.

51. (NEW) The dosage form of claim 47, wherein said at least one crosslinked hydrodynamic fluid-imbibing polymer has a swell capacity in a fluid environment of between about 1 weight % to about 3000 weight %.

52. (NEW) The dosage form of claim 47, wherein said at least one crosslinked hydrostatic pressure-modulating agent is a rapidly swelling polymer having a swell capacity in a fluid environment of between about 0.5 weight % to about 500 weight %.

53. (NEW) The dosage form of claim 47, wherein said pharmacologically-active substance is released in a controlled manner with zero-order or near zero-order release kinetics over a therapeutically practical time period following administration of said dosage form.

54. (Canceled)

55. (Canceled)

56. (*currently amended*) A dosage form for oral administration consisting of:

a compressed homogeneous mixture comprising:

a pharmacologically-active substance; and

a hydrostatic couple consisting of:

a) at least one crosslinked hydrodynamic fluid-imbibing polymer selected from the group consisting of:

i) an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol;

ii) one or more [starch derivatives] high amylose starches cross-linked by epichlorhydrin,

phosphorous oxychloride ($POCl_3$), or sodium trimetaphosphate;

iii) a crosslinked polyglucan;

iv) a crosslinked polyethylenimine;

v) a crosslinked polyallylamine, and

vi) combinations thereof; and

b) at least one crosslinked hydrostatic pressure-modulating agent selected from the group consisting of:

i) a homopolymer of cross-linked N-vinyl-2-pyrollidone;

ii) a rapidly expanding cross-linked cellulose derivative selected from the group consisting of cross-linked carboxymethyl cellulose, sodium starch glycolate, and combinations thereof; and

iii) combinations thereof; and

c) an expansion source.

57. (NEW) The dosage form of claim 56, wherein said expansion source is selected from the group consisting of a carbon-dioxide precursor, an oxygen precursor, and a chlorine dioxide precursor.

58. (NEW) The dosage form of claim 57, wherein said carbon dioxide precursor is selected from the group consisting of carbonates, sesquicarbonate, hydrogen carbonate, potassium carbonate, lithium carbonate, sodium carbonate, ammonium carbonate, sodium amino acid carbonate, sodium glycine carbonate, L-lysine carbonate and arginine carbonate.

59. (NEW) The dosage form of claim 57, wherein said oxygen precursor is selected from the group consisting of sodium percarbonate, sodium perborate monohydrate, anhydrous sodium perborate, effervescent perborate, and .sodium dichloroisocyannurate.

60. (NEW) The dosage form of claim 57, wherein said chlorine dioxide precursor is selected from the group consisting of sodium hypochlorite and calcium hypochlorite.

61-74 (Canceled)

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: The primary reasons for allowance is that the consisting language of the claims excludes layered or multiple layered dosage forms because the layer(s) is not part of the homogeneous mixture of pharmacological agent and the hydrostatic couple.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618